DOCKET NO.: PUJ-0279 **PATENT**

Application No.: 09/634,399

Office Action Dated: June 24, 2005

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims:

1. (Currently amended) A composition in the form of a single-phase gel comprising

from greater than about 5% to about 8% minoxidil, a crosslinked copolymer of acrylic acid as

a thickening agent, and a pharmaceutically acceptable solvent, wherein said minoxidil is

present at a concentration which is less than its solubility limit in said composition.

2 - 4. (Cancelled)

5. (Previously Presented) A composition of claim 1 which comprises from about 5%

to about 6% minoxidil.

(Original) A composition of claim 5 which comprises about 5% minoxidil. 6.

7. (Currently amended) A composition of claim 1, wherein said pharmaceutically

acceptable solvent is selected from the group consisting of alcohols and polyols ethanol,

propanol, butanol, propylene glycol, dipropylene glycol, hexylene glycol, 1,3-butylene

glycol, PEG-200, PEG-400, glycerol and mixtures thereof.

8. (Currently amended) A composition of claim 7, wherein said solvent comprises an

alcohol comprising a solvent selected from the group consisting of ethanol, propanol and

butanol.

9. (Canceled)

(Currently amended) A composition of claim 9 8, wherein said alcohol is 10.

comprising a solvent selected from the group consisting of ethanol and isopropanol.

11. (Canceled)

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12. (Canceled)

13. (Currently amended) A composition of claim 12 7, wherein said glycol is comprising a solvent selected from the group consisting of propylene glycol, dipropylene glycol, hexylene glycol, 1,3-butylene glycol, PEG-200, PEG-400, and glycerol.

- 14 (Currently amended) A composition of claim 13, wherein said glycol is solvent comprises propylene glycol.
- 15. (Currently amended) A composition of claim 7, wherein said solvent comprises a mixture of an alcohol and a glycol mixture comprising a first solvent selected from the group consisting of ethanol, propanol and butanol and a second solvent selected from the group consisting of propylene glycol, dipropylene glycol, hexylene glycol, 1,3-butylene glycol, PEG-200, PEG-400, and glycerol.
- 16. (**Original**) A composition of claim 15, wherein said solvent comprises a mixture of ethanol and propylene glycol.
- 17. (Original) A composition of claim 1, further comprising a neutralizing agent.
- 18. (**Original**) A composition of claim 17, wherein said neutralizing agent is selected from the group consisting of ammonium hydroxide, arginine, 2-amino-2-methyl-1-propanol, dimethanolamine, dibutanolamine, diisobutanolamine, tributanolamine, triisobutanolamine, tri-sec-butanolamine, tripropylamine, ethanolamine, diethanolamine, triethanolamine, PEG-15 cocamine, diisopropanolamine, methylethanolamine, diisopropylamine, dipropylenetriamine, tromethamine, isopropylamine ethylene diamine, triisopropanolamine, tetrahydroxypropyl ethylenediamine, trimethamine, 2-aminobutanol, aminoethyl propanediol, aminomethyl propanediol, sodium hydroxide, and potassium hydroxide.

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- 19. (**Original**) A composition of claim 18, wherein said neutralizing agent is selected from the group consisting of 2-amino-2-methyl-1-propanol, diisopropanolamine, triisopropanolamine, and tetrahydroxypropyl ethylenediamine.
- 20. (**Original**) A composition of claim 19, wherein said neutralizing agent is 2-amino-2-methyl-1-propanol.
- 21. (Original) A composition of claim 1, wherein said solvent is present in said composition in an amount of at least about 20%.
- 22. (Previously presented) A composition of claim 21 which comprises from about 20% to about 99% of said solvent.
- 23. (Canceled)
- 24 29. (Cancelled)
- 30. (Previously presented) A composition of claim 1, wherein said crosslinked copolymer of acrylic acid comprises an acrylate/ C_{10-30} alkyl acrylate crosspolymer.
- 31 34. (Cancelled)
- 35. (Previously presented) A composition of claim 30 wherein said solvent is present in said composition in an amount of at least about 20%.
- 36. (Currently amended) A high solvent/low water composition in the form of a single-phase gel comprising about 5% to about 8% minoxidil, greater than about 50% of a pharmaceutically acceptable solvent selected from the group consisting of alcohols comprising a first solvent selected from the group consisting of ethanol, propanol and butanol, and a second solvent selected from the group consisting of propylene glycol, dipropylene glycol, hexylene glycol, 1,3-butylene glycol, PEG-200, PEG-400, glycerol and

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mixtures thereof, up to about 25% water, and a solvent-tolerant carbomer, wherein said minoxidil is present at a concentration which is less than its solubility limit in said composition.

37 - 38. (Cancelled)

- 39. (Previously presented) A composition of claim 36 which comprises from about 5% to about 7% minoxidil.
- 40. (Original) A composition of claim 39 which comprises from about 5% to about 6% minoxidil.
- 41. (Original) A composition of claim 40 which comprises about 5% minoxidil.
- 42. (Cancelled)
- 43. (Currently amended) A composition of claim 36, wherein said solvent comprises an alcohol comprising a solvent selected from the group consisting of ethanol, propanol, and butanol.
- 44. (Canceled)
- 45. (Currently amended) A composition of claim 44 <u>43</u> wherein said alcohol is comprising a solvent selected from the group consisting of ethanol and isopropanol.
- 46. (Currently amended) A composition of claim 36 wherein said comprising a solvent comprises a polyol selected from the group consisting of propylene glycol, dipropylene glycol, hexylene glycol, 1,3-butylene glycol, PEG-200, PEG-400, and glycerol.
- 47. (Canceled)

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- 48. (Canceled)
- 49. (Currently amended) A composition of claim 48 <u>46</u>, wherein said glycol is comprising propylene glycol.
- 50. (Currently amended) A composition of claim 36, wherein said solvent comprises a mixture of an alcohol and a glycol mixture comprising a first solvent selected from the group consisting of ethanol, propanol and butanol and a second solvent selected from the group consisting of propylene glycol, dipropylene glycol, hexylene glycol, 1,3-butylene glycol, PEG-200, PEG-400, and glycerol.
- 51. (**Original**) A composition of claim 50, wherein said solvent comprises a mixture of ethanol and propylene glycol.
- 52. (Previously presented) A composition of claim 36, further comprising a neutralizing agent.
- 53. (**Original**) A composition of claim 52, wherein said neutralizing agent is selected from the group consisting of arginine, 2-amino-2-methyl-1-propanol, dimethanolamine, dibutanolamine, diisobutanolamine, tributanolamine, triisobutanolamine, tri-secbutanolamine, tripropylamine, ethanolamine, diethanolamine, triethanolamine, PEG-15 cocamine, diisopropanolamine, methylethanolamine, diisopropylamine, dipropylenetriamine, tromethamine, isopropylamine ethylene diamine, triisopropanolamine, tetrahydroxypropyl ethylenediamine, trimethamine, 2-aminobutanol, aminoethyl propanediol, aminomethyl propanediol, and aminomethyl propanol.
- 54. (**Original**) A composition of claim 53, wherein said neutralizing agent is selected from the group consisting of 2-amino-2-methyl-1-propanol, diisopropanolamine, triisopropanolamine, and tetrahydroxypropyl ethylenediamine.

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55. (**Original**) A composition of claim 54, wherein said neutralizing agent is 2-amino-2-methyl-1-propanol.

56. (Cancelled)

- 57. (**Previously presented**) A composition of claim 36 which comprises from about 20% to about 99% of said solvent.
- 58. (**Previously presented**) A composition of claim 57 wherein the ratio of said solvent to minoxidil is about 10:1.
- 59. (**Previously presented**) A composition of claim 58 wherein the ratio of said solvent to minoxidil is about 12:1.
- 60. (**Previously presented**) A composition of claim 59 wherein the ratio of said solvent to minoxidil is about 15:1.
- 61. (Canceled)
- 62. (Currently amended) A composition in the form of a single-phase gel comprising: from greater than about 5% to about 8% of minoxidil;

from about 30% to about 80% of a polyol first solvent selected from the group consisting of propylene glycol, dipropylene glycol, hexylene glycol, 1,3-butylene glycol, PEG-200, PEG-400, and glycerol;

from about 10% to about 50% of an alcohol second solvent selected from the group consisting of ethanol, propanol and butanol;

from about 0.01% to about 50% of a crosslinked copolymer of acrylic acid; Page 7 of 19

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from about 0% to about 3% of a neutralizing agent; and

water (qs);

wherein said minoxidil is present at a concentration which is less than its solubility limit in said composition.

- 63. (Cancelled)
- 64. (Canceled)
- 65. (Canceled)
- 66. (Currently amended) A composition of claim 65 62, wherein said glycol first solvent is propylene glycol.
- 67. (Canceled)
- 68. (Currently amended) A composition of claim 67 62, wherein said alcohol second solvent is selected from the group consisting of ethanol and isopropanol.
- 69. (Canceled)
- 70. (**Previously presented**) A composition of claim 62 wherein said crosslinked copolymer of acrylic acid comprises an acrylate/C₁₀₋₃₀ alkyl acrylate crosspolymer.
- 71. (Original) A composition of claim 62, wherein said neutralizing agent is selected from the group consisting of arginine, 2-amino-2-methyl-1-propanol, dimethanolamine, dibutanolamine, diisobutanolamine, tributanolamine, triisobutanolamine, tri-secbutanolamine, tripropylamine, ethanolamine, diethanolamine, triethanolamine, PEG-15 cocamine, diisopropanolamine, methylethanolamine, diisopropylamine, dipropylenetriamine,

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tromethamine, isopropylamine ethylene diamine, triisopropanolamine, tetrahydroxypropyl ethylenediamine, trimethamine, 2-aminobutanol, aminoethyl propanediol, aminomethyl propanediol, and aminomethyl propanol.

- 72. (**Original**) A composition of claim 71, wherein said neutralizing agent is selected from the group consisting of 2-amino-2-methyl-1-propanol, diisopropanolamine, triisopropanolamine, and tetrahydroxypropyl ethylenediamine, and mixtures thereof.
- 73. (**Original**) A composition of claim 72, wherein said neutralizing agent is 2-amino-2-methyl-1-propanol.
- 74. (Currently amended) A composition of claim 62, comprising: from about 5% to about 7% of minoxidil; from about 40% to about 70% of a polyol said first solvent; from about 20% to about 30% of an alcohol said second solvent; from about 0.05% to about 3% of a crosslinked copolymer of acrylic acid; and from about 0.03% to about 1% of a neutralizing agent.
- 75. (Currently amended) A composition of claim 74, comprising: from about 5% to about 6% of minoxidil; from about 50% to about 60% of a polyol said first solvent; and from about 25% to about 30% of an alcohol said second solvent.
- 76. (Currently amended) A composition of claim 74 comprising: about 5% of minoxidil; about 53% of a polyol said first solvent; and about 26% of an alcohol said second solvent; from about 0.25% to about 1% of a crosslinked copolymer of acrylic acid; and from about 0.15% to about 0.6% of a neutralizing agent.

77 - 110. (Cancelled)

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(Previously presented) A method comprising topically administering a composition 111.

according to claim 1 to a region of hair loss on a patient.

(Currently amended) A method according to claim 111, wherein said hair loss 112.

eomprises androgenetic is selected from the group consisting of androgenic alopecia, frontal

hair loss, bitemporal recession, vertex balding, mid-anterior balding, alopecia areata, anagen

hair loss, diffuse alopecia, and telogen effluvium.

(Previously presented) A method comprising topically administering a composition 113.

according to claim 36 to a region of hair loss on a patient.

(Currently amended) A method according to claim 113, wherein said hair loss 114.

comprises androgenetic is selected from the group consisting of androgenic alopecia, frontal

hair loss, bitemporal recession, vertex balding, mid-anterior balding, alopecia areata, anagen

hair loss, diffuse alopecia, and telogen effluvium.

(Previously presented) A method comprising topically administering a composition 115.

according to claim 62 to a region of hair loss on a patient.

116. (Currently amended) A method according to claim 115, wherein said hair loss

comprises androgenetic is selected from the group consisting of androgenic alopecia, frontal

hair loss, bitemporal recession, vertex balding, mid-anterior balding, alopecia areata, anagen

hair loss, diffuse alopecia, and telogen effluvium.

117 - 119. (Cancelled)

120. (Currently amended) A composition of claim 36 comprising:

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from about 5% to about 7% of minoxidil;

from about 40% to about 70% of a polyol said second solvent;

from about 20% to about 30% of an alcohol said first solvent;

from about 0.05% to about 3% of an acrylate/C₁₀₋₃₀ alkyl acrylate crosspolymer.

121. (Currently amended) A composition of claim 120 comprising:

from about 5% to about 6% of minoxidil;

from about 50% to about 60% of a polyol said second solvent; and

from about 25% to about 30% of an alcohol said first solvent.

122. (Currently amended) A composition of claim 121 comprising:

about 5% of minoxidil;

about 53% of a polyol said second solvent;

about 26% of an alcohol said first solvent;

from about 0.25% to about 1% of an acrylate/C₁₀₋₃₀ alkyl acrylate crosspolymer.

123. (Newly added) A composition in the form of a single-phase gel consisting essentially of:

from about 5% to about 8% of minoxidil;

from about 30% to about 80% of a first solvent selected from the group consisting of propylene glycol, dipropylene glycol, hexylene glycol, 1,3-butylene glycol, PEG-200, PEG-400, and glycerol;

from about 10% to about 50% of a second solvent selected from the group consisting of ethanol, propanol and butanol;

from about 0.01% to about 50% of a crosslinked copolymer of acrylic acid;

from about 0% to about 3% of a neutralizing agent;

optionally, one or more pharmaceutically acceptable additives or ingredients selected from the group consisting of hair conditioners, panthenol, calcium pantothenate, colorants, fragrances, vitamin E, penetration modifiers, surfactants, cosmetic agents, fatty acids and fatty acid esters, herbal extracts, henna, emulsifiers, wetting agents, sunscreens, and anti-irritants; and

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water (qs);

wherein said minoxidil is present at a concentration which is less than its solubility limit in said composition.

- 124. (Newly added) A composition of claim 123, wherein said first solvent is propylene glycol.
- 125. (Newly added) A composition of claim 123, wherein said second solvent is selected from the group consisting of ethanol and isopropanol.
- 126. (Newly added) A composition of claim 123, wherein said crosslinked copolymer of acrylic acid is an acrylate/ C_{10-30} alkyl acrylate crosspolymer.
- 127. (Newly added) A composition of claim 123, wherein said neutralizing agent is selected from the group consisting of arginine, 2-amino-2-methyl-1-propanol, dimethanolamine, dibutanolamine, diisobutanolamine, tributanolamine, triisobutanolamine, tri-sec-butanolamine, tripropylamine, ethanolamine, diethanolamine, triethanolamine, PEG-15 cocamine, diisopropanolamine, methylethanolamine, diisopropylamine, dipropylenetriamine, tromethamine, isopropylamine ethylene diamine, triisopropanolamine, tetrahydroxypropyl ethylenediamine, trimethamine, 2-aminobutanol, aminoethyl propanediol, aminomethyl propanediol, and aminomethyl propanol.
- 128. (Newly added) A composition of claim 127, wherein said neutralizing agent is selected from the group consisting of 2-amino-2-methyl-1-propanol, disopropanolamine, triisopropanolamine, and tetrahydroxypropyl ethylenediamine, and mixtures thereof.
- 129. (Newly added) A composition of claim 128, wherein said neutralizing agent is 2-amino-2-methyl-1-propanol.
- 130. (Newly added) A composition of claim 123, comprising: from about 5% to about 7% of minoxidil;

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from about 40% to about 70% of said first solvent;

from about 20% to about 30% of said second solvent; and

from about 0.05% to about 3% of a crosslinked copolymer of acrylic acid.

131. (Newly added) A composition of claim 130, comprising:

from about 5% to about 6% of minoxidil;

from about 50% to about 60% of said first solvent; and

from about 25% to about 30% of said second solvent.

132. (Newly added) A composition of claim 131 comprising:

about 5% of minoxidil;

about 53% of said first solvent;

about 26% of said second solvent; and

from about 0.25% to about 1% of a crosslinked copolymer of acrylic acid.

133. (Newly added) A method comprising topically administering a composition according to claim 123 to a region of hair loss on a patient.

134. (Newly added) A method according to claim 133, wherein said hair loss is selected from the group consisting of androgenic alopecia, frontal hair loss, bitemporal recession, vertex balding, mid-anterior balding, alopecia areata, anagen hair loss, diffuse alopecia, and telogen effluvium.